K110996

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MAY 10 2011

Section 8
510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

Submitted by:

Cochlear Americas
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Centennial, CO 80111

On behalf of:

Cochlear Bone Anchored Solutions AB
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Contact Persons:

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Date Submission Prepared:

March-April 2011

Device Name:

Trade or Proprietary Name:	Cochlear Baha® BP110 Power
Common or Usual Name:	Sound Processor
Classification Status:	Class II, 21 CFR §874.3300
Product Codes:	LXB
Panel:	Ear Nose and Throat Specialty Panel

Device Description:

The subject of this **Special 510(k): Device Modification** is a modification to the Cochlear Baha® Intenso sound processor, which was cleared under 510(k) K081606 for unilateral or bilateral use with conductive and mixed hearing losses (as a result of congenital malformations such as atresia, or certain medical conditions such as chronic suppurative otitis media), and for cases of single-sided sensorineural deafness (SSD, caused by a congenital condition, surgery, trauma or disease). The Baha system has been marketed for more than 30 years throughout the world, and there are now more than 77,000 users of a Baha system globally.

Baha sound processors can be used with either the external Baha headband or Softband, or, for children aged 5 or older, with the Baha auditory osseointegrated implants. The external Baha headband or Softband system works via conventional transcutaneous bone conduction amplification. The Baha implant system works by combining the external sound processor with an abutment and a small titanium implant placed in the skull behind the ear in a simple surgical procedure. The system is based on the process of "osseointegration" through which living tissue integrates with titanium in the implant. Thus, the titanium implant becomes one with the surrounding bone, allowing high-quality amplified and processed sound from the Baha sound processor to be conducted via the skull bone directly to a cochlea with residual functionality. For either form of transmission, the processed sound either bypasses a conductive block in those patients with conductive or mixed hearing loss, or transfers sound through the skull to the opposite-ear normal cochlea for patients with SSD.

The modified sound processor, the Baha BP110 Power is an upgrade to the currently marketed Baha Intenso sound processor, which it will replace on the U.S. market. The BP110 Power sound processor will provide a more modern device with technological innovations compared to the predicate Intenso. As the modified device utilizes the same fundamental scientific principles, and the same intended use and indications for use as the current legally marketed device it will replace, and merely represents improvements in features and the sound processing of the amplified sound that are the same as those used in another Cochlear Baha sound processor that has already been cleared for marketing for a less hearing-impaired population (the model BP100, cleared under K090720), we believe these modifications are appropriate for the Special 510(k) process.

Intended Use:

The new Baha BP110 Power will be used as an external sound processor option (in the Cochlear Baha family of sound processors) to conduct sound energy directly to the cochlea via a Baha auditory osseointegrated implant, or via transcutaneous

transmission with a Baha headband or Softband. This is the same intended use, and for the same patient population, as the current legally marketed, unmodified Baha Intenso device (the predicate device that it will replace).

Technological Characteristics:

The modified sound processor will still be compatible with the currently marketed Softband/headband (cleared under K002913 and letters to file under this clearance), and the currently marketed auditory osseointegrated implant (BIA300 system, cleared under K100360), and will also be backward compatible with the original auditory osseointegrated implant (cleared under K955713).

The primary modifications proposed are technological improvements so that the BP110 Power will be digitally programmable, allow up to three user-selectable listening programs and measurement of direct bone conduction thresholds (through the sound processor) for greater accuracy in fitting, and provide a number of sound processing improvements and features that have already been cleared for another Baha sound processor intended for a less severely impaired population (the Baha BP100, cleared under K090720). Improvements in sound processing include multi-channel, non-linear programmability, advanced automatic directionality, background noise management, active feedback cancellation, and position compensation. The BP110 Power can be fit with Baha Fitting Software (also previously cleared under K090702), which has proprietary amplification strategies for direct bone conduction delivery of amplified sound. The BP110 Power also has audible and visible indicators (LEDs and beeps) for monitoring the status of the sound processor, a Europlug for compatibility with standard accessories and mainstream FM devices, and tamper proof features for the pediatric population. These modifications will result in a device that will provide more individual flexibility and accuracy in fitting and an increased number of sound processing options and features currently found in air conduction hearing aids (Class I, Exempt).

Conclusions:

Despite technological improvements and the upgrade to new sound processing features, the Baha BP110 Power sound processor still has substantially equivalent function and technology, and the same intended use as the predicate Baha Intenso sound processor cleared for marketing under K081606. The indication for use statement is also the same as that for the current legally marketed Baha Intenso sound processor that it will replace.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 10 2011

Cochlear Americas
c/o Sean Bundy
Sr. Manager Affairs and Compliance
13059 East Peakview Ave.
Centennial, CO 80111

Re: K110996
Trade/Device Name: Cochlear™ Baha® BP110 Power Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: April 8, 2011
Received: April 11, 2011

Dear Mr. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110996

Device Name: Cochlear Baha® BP110 Power Sound Processor

Indications for Use Statement:

The Cochlear Baha® BP110 Power sound processor has the following indications for use:

- Patients of any age for use with the Baha Softband or headband. Patients aged 5 and older for use with the Baha auditory osseointegrated implant system.

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dB HL.

- Bilateral fitting is intended for patients who meet the criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single-Sided Deafness; SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.

- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Prescription Use ___X____ (21 CFR 801 Subpart C) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110996